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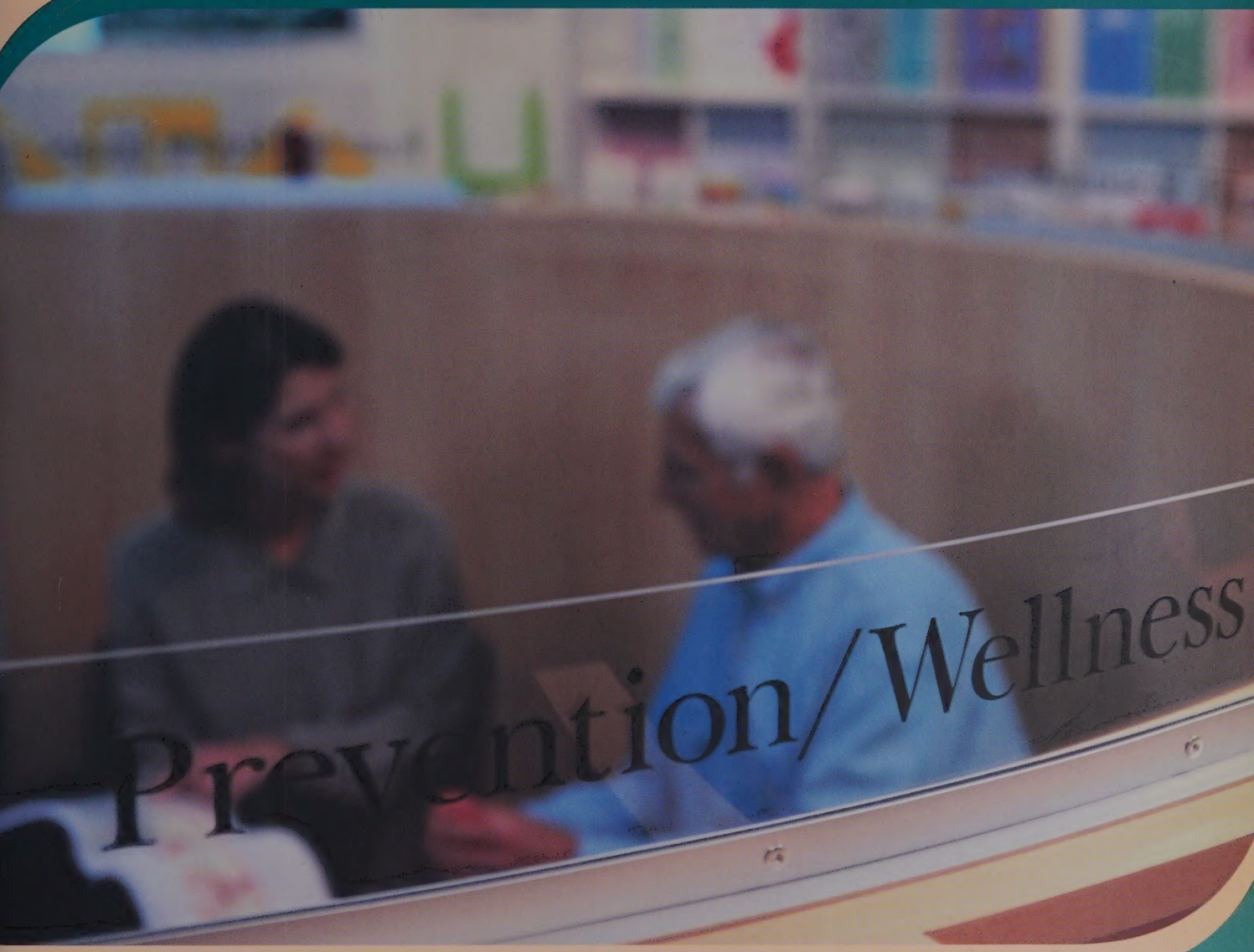

Research**strategy**
for Health and Healthcare

Revised July 2003

CHIEF SCIENTIST

SCOTTISH EXECUTIVE

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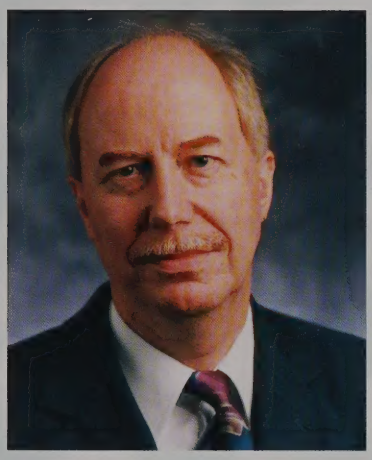


Foreword

This document aims to ensure that healthcare delivery is informed by quality research. In achieving this aim it is essential that there is robust governance of research and that the public can place confidence in all aspects of the process. Patients must benefit from scientific advances and healthcare organisations need to make the most effective use of the resources at their disposal.

That is why this strategy document seeks to increase the awareness of the need to identify research requirements and to ensure that these are widely known by all those able to play a part. There is a need to integrate research more fully into the agenda of most NHS organisations, to encourage research activity and, as importantly, its usage.

Research represents a significant investment in the future delivery of health and healthcare. Central to the strategy is the need to ensure that expenditure on research is as well focused as possible to achieve the objectives of improving health and health services for the people of Scotland. The strategy aims to ensure that there is a common understanding of the main priorities for research. It sets a framework within which we can all work together and, if necessary, respond to new priorities as they emerge.

Malcolm Chisholm

MALCOLM CHISHOLM, MSP
Minister for Health and Community Care

RESEARCH STRATEGY FOR HEALTH AND HEALTHCARE – 2003

Executive Summary

This document is about improving the scope, relevance and quality of research for the health and healthcare needs of the people of Scotland. Policy and practice in healthcare should both be founded on the best evidence available. The need to translate research findings into practical benefits remains as important now as in 1993 when the first Chief Scientist Office (CSO) Strategy was published.

Much has changed since the first Strategy was published. CSO has a devolved budget that must strike a balance between supporting an appropriate breadth of work relevant to the people of Scotland and their healthcare needs whilst also ensuring that meaningful support is available to priority topics. The three clinical priorities remain *Mental Health; Coronary Heart Disease and Stroke;* and *Cancer.* This document describes how the work considered to be of greatest importance within these heads will be identified. A portfolio of work is under development for each topic that will be managed pro-actively with gaps being targeted for future funding.

Preventing disease must also be a key component of our Strategy for research funding in the next five years and we shall be working with the relevant parties to develop a cohesive portfolio of work in this area.

The NHS is an innovative and research active environment. It is essential that good ideas are taken into wider practice and that those with commercial potential are identified and promoted. A company, Scottish Health Innovations Ltd has been formed by Scottish Enterprise to be responsible for technology transfer for NHSScotland. It will also aim to heighten awareness of the importance and relevance of intellectual property.

The last few years have also witnessed changes in the roles of Health Boards and hospitals as well as considerable evolution in primary care. These changes will continue and the contributions and benefits each might make and receive from an active research programme are becoming ever more apparent. This Strategy sets an ambitious agenda to continue the cultural change initiated in the last few years. It provides a framework to which the managers, researchers, consumers and the full spectrum of healthcare professions can contribute. We would encourage the fullest involvement and commend the Strategy to all those with responsibility for improving health, healthcare and its delivery.

T JONES
Head of Health Department
Chief Executive, NHSScotland

R JUNG
Chief Scientist

Introduction

AIMS

This research strategy will aim to help secure lasting improvements to the health of the people in Scotland and improve the quality and cost-effectiveness of health services and healthcare.

OBJECTIVES

In order to achieve these ambitious aims, the Chief Scientist Office (CSO) will support high quality research in priority areas of relevance to healthcare in Scotland and

1. Work with others to identify topics which are important to the NHS and health improvement, and amenable to research;
2. Commission studies in areas of particular importance;
3. Promote a multidisciplinary approach to health services research;
4. Encourage implementation of relevant research findings and innovations;
5. Strengthen the system of Research Governance;
6. Develop portfolios of work in relevant topics;
7. Increase research capacity in under-developed fields;
8. Encourage increased co-operative working;
9. Refine the allocation formula meeting research infrastructure costs in the NHS;
10. Maintain support for high quality projects proposed by individual researchers and groups.

1 Overview

Background

The Scottish Executive Health Department (and its predecessor Departments) has funded research through the Chief Scientist Office (CSO) since 1973. Its first Research Strategy was produced in 1993 and was last revised in 1998. This Strategy is also planned with a five-year horizon in mind. CSO has a remit to encourage and support research to improve the health of the people in Scotland and the services provided by the NHS. Increasingly however, such organisational boundaries are being eroded and it will be important that research questions reflect the partnership arrangements between the NHS and local authorities across Scotland.

CSO has a budget of around £47 million per annum. This money is spent both directly in support of individuals, projects, programmes and Units, and indirectly by allocating money to support research in the health service. At present some £33 million is spent on the latter and £14 million represents direct expenditure.

Context/environment

The context in which CSO operates has changed markedly over the last five years. The formation of the Scottish Parliament is producing more pronounced differences in the policy environment and there is an increased recognition of the need for evidence to support its growing agenda. CSO has always sought to fund research able to address relevant issues and capable of ready application. More basic research is supported by funders such as the Medical Research Council that funds UK-wide and with whom we have a close working relationship.

CSO is responsible for a devolved budget. It is one of the key budgets underpinning the *Science Strategy for Scotland* published in 2001 which emphasised the importance of science and the qualitative, as well as the economic, benefits to which the nation should aspire. Although indicating that fields, such as bio-technology, would clearly be key to delivery, in general it declined to suggest specific priorities. This document sets out those for health.

Devolution has had a significant effect, although its true impact is still not widely appreciated by the research community. Increasingly, there is a greater divergence in policy by each UK Health Department and less flexibility about use of funds should the recipient cross a border during the funding period.

Some aspects of science policy (such as intellectual property) remain reserved. The mixture of reserved and devolved matters has the potential to create practical challenges and CSO must seek compromises that recognise the Scottish situation. Equally, it is increasingly recognised that the public sector funders in the UK must work together if best value is to be won from the overall public investment in research. Funders' Fora have been established in cancer (now the National Cancer Research Institute), cardiovascular disease (CVD) and diseases of ageing and the elderly. Each includes all four UK Departments of Health, the Medical Research Council (MRC) and appropriate larger research funders from the charitable sector. Such arrangements are discussed in chapter 7. Likewise, UK-wide agreements have been reached for research funded by the pharmaceutical industry.

Research is also increasingly affected by the impact of EU legislation. The EU Clinical Trials Directive is one of the most obvious examples, with far-reaching implications for patient safety and the conduct of research involving patients, their organs, tissue or data. This is explored in greater depth in chapter 4.

The Research Assessment Exercise, conducted in 2001, demonstrated generally improved quality across the sector, with some noticeable exceptions that are addressed in future chapters. It also served to emphasise some past concerns with process. CSO will work with the Higher Education Funding Councils to improve recognition for research relevant to the NHS. Equally, it is more important than ever that researchers

strive to achieve international recognition while building on the creative tensions inspired by local competition.

Budgetary pressures are now becoming increasingly commonplace for healthcare research funders, such that even proposals of undeniably high quality can no longer be guaranteed support. During the life of the last Research Strategy, CSO gave a high priority to improving scientific quality and, as a result, has only recently found itself in the same position. This Strategy must therefore address a number of choices in determining the most effective role for CSO.

While the scientific and clinical communities have always played a large part in priority setting, greater involvement of the public is also essential and we have tried to address that both in the consultation and this resulting document. There has been progressively greater emphasis attached to involving patients and 'consumers' of healthcare in its delivery. Participation in the research agenda is clearly a desirable part of this aim and CSO's approach is described in chapter 4.

... it is increasingly recognised that the public sector funders in the UK must work together if best value is to be won from the overall public investment in research.

Scottish Executive policy/NHS change

In recent years, increasing importance has been given to:

- addressing inequalities in health and access to healthcare;
- devising and applying quality standards for healthcare;
- assessing new healthcare technologies;
- more coherent and cohesive training opportunities for healthcare professions.

A number of new organisations and arrangements have been created to address these needs. The Public Health Institute for Scotland, formed in 2001, and now combined with the Health Education Board for Scotland to form a single health improvement organisation, NHS Health Scotland, aims to provide leadership to the health improvement agenda, focus on implementation of health improvement programmes and to develop the health improvement research and evidence base. The Health Technology and Clinical Standards Boards (now both within NHS Quality Improvement Scotland – NHS QIS), combined with the progressive formation of managed clinical networks, are helping to tackle the first three points above. The last bullet point is being addressed by NHS Education for Scotland (NES), formed by the amalgamation of several predecessor training bodies for separate healthcare professions.

Each of these changes create new agenda for research and opportunities for CSO to adapt and innovate.

Achievements

There have been some major achievements during the last five years, many of which relate to the objectives described in the 1998 Strategy. All 10 specific objectives set then have been achieved or significant progress has been made. These are summarised in Annex 1. Our Annual Report for 2002-03 provides a more detailed account.

Support for all scientific priorities identified then tended to grow, with significant extra resources being found to support cancer, particularly cancer trials. Core funded Units have focused their activities and their programmes of research have improved relevance to healthcare delivery and issues for policy and decision makers. They continue to help to build capacity in under-developed subjects. Capacity building has proved especially effective for health services research and excellent fields are attracted to annual competitions for such awards.

The next five years

Some of the agenda is already set. In the next five years we need to:

- implement research governance fully;
- improve patient/consumer involvement with our work;
- be more proactive in managing our research programmes (ensuring an appropriate proportion of expenditure is in priority areas);
- oversee development of programmes from NHS 'own account' work, more closely linked to priorities (local or national);
- participate in large population-based studies
- continue to build capacity in primary care, nursing, midwifery, and allied health professions;
- address issues of under-supply in disciplines such as statistics and epidemiology;
- encourage research training amongst clinical trainees in collaboration with NHS Education for Scotland.

In addition, the consultation process (described in Annex 2) raised further aspects:

- focus more clearly on the applied end of the research-funding spectrum;
- give greater focus to holistic/quality of life models;
- effective engagement with Quality Improvement Scotland and NHS Health Scotland to support each others' agenda;
- encourage more effective implementation of research.

Tensions and choices

The initial consultation process gave strong support to the dualism that CSO has championed in the past: focusing a significant proportion of resources on priorities while also encouraging a broad range of research that helps to sustain a wide spectrum of skills. CSO was felt to fill a unique niche in Scotland, providing capacity-building opportunities for skills key to its health service. Its funds also create excellent leverage and the Scottish health care research community is conspicuously successful in winning funding from many other prestigious bodies such as MRC, the Wellcome Trust and Cancer Research UK.

While this role continues to attract support, potentially it leaves little scope for new areas. The consultation identified some possibilities for exciting new initiatives but priorities must be determined, choices must be made and finite resources allocated accordingly. The remaining chapters of this Strategy seek to address these issues and to propose the focus of activity for CSO in the next five years.

CSO was felt to fill a unique niche in Scotland, providing capacity-building opportunities for skills key to its health service.

2 Research in Priority Areas

The recommendation from the review of CSO funding streams in 2000 was that CSO should pursue the funding of priority topics in a more targeted manner and that funding should follow quality. These principles have shaped and guided the subsequent work to revise the mechanism for allocation of Support Costs, and this is described more fully in chapter 5. In terms of CSO's direct expenditure on research, this places a greater emphasis on proactively managing the research budget to ensure an appropriate expenditure in priority areas.

The consultation process suggested that there would be considerable support for CSO funding priorities to be those areas most likely to produce most benefit to most people. We have interpreted this to mean that there remains strong support for significant resources going to the three clinical priority areas of cancer, CVD/stroke, and mental health with an expansion of research on public health.

Inevitably, identifying a few topics as priorities may be felt to have implications for the wider funding support available from CSO and this is addressed in greater detail in chapter 3. The focus on these four clinical priorities was arrived at after much discussion. Alternatives, such as symptom management, rehabilitation, organisation of care, etc. are cross-cutting aspects but ones which we expect to feature within the broad portfolio groupings chosen. Similarly, it is essential that work on child health and care of the elderly feature strongly and transcend portfolio boundaries.

The initial consultation made it clear that:

- CSO should sustain its role as a funder of applied research to enable advances in basic science to be translated into benefit to the patient;
- developing capacity in health services research should continue to be supported;
- research relevant to the needs of the elderly population should be increased;
- sustaining growth in primary care research remained important.

Certain generic issues were also raised, particularly relating to the administrative burden of clinical trials. CSO will work with other stakeholders to try to simplify and refine the processes involved.

Portfolio management

It has only recently become possible for CSO to take an informed overview of all its direct and indirect support to research on a particular topic. This allows a more complete overview of activity to be taken. The four top priorities identified above will now be managed as portfolios. Each portfolio will embrace all relevant CSO funded work in a priority area. This expenditure will primarily comprise existing commitments to ongoing projects, new response mode projects in priority areas funded through the two grant-awarding committees and commissioned research instigated by the portfolio steering groups.

Portfolio steering groups for the four priority areas will be composed of a wide representation from the research area, policy makers and consumers/patients. Their role will be to assist CSO to manage its research portfolios strategically by identifying areas where targeted research is needed or would make a significant impact. This view will be informed by taking into account research funded by CSO and others, as well as research needs identified by agencies such as the Scottish Intercollegiate Guidelines Network (SIGN) and NHSQIS. This process has been aided by the formation of funders' fora that are working to build a picture of ongoing funded research in the UK (these are described in more detail in chapter 7).

It is likely that the different steering groups will adopt quite different approaches to commissioning research

or building capacity in different areas, according to the strengths and weaknesses identified in those areas. The aim of the portfolios is to develop a flexible and dynamic approach to support research in these priority areas. Commissioning will not be restricted to didactic research initiatives but will focus on quality and relevance.

It also remains essential that all research supported by CSO is designed to ensure that the relevant patient groups are recruited properly to address the questions posed. Issues such as gender, race, ethnicity and disability must be taken into account appropriately, recognising that this may require oversampling in some situations. In order to comply with the Race Relations (Amendment) Act 2000, the Health Department is obliged to ensure that race and ethnicity are appropriately considered in the planning and commissioning of any research that they propose to support.

... there would be considerable support for CSO funding priorities to be those areas most likely to produce most benefit to most people.

Cancer portfolio

Without any strategic management, CSO's direct spend on cancer research projects was £1.74 million for 2002-03 (c.14% of CSO's total direct research spend). The large majority of this expenditure arises from spontaneous grant applications, many of them aiming to establish the pathological significance of key genetic mutations in breast, colorectal and ovarian cancers, both in terms of susceptibility to disease and prognosis. However, there are also several Training Fellowships on cancer-related topics and a programme of cancer research within our core funded Nursing Research Initiative for Scotland. Cancer research also accounts for a large proportion (c.25%) of the R&D Support Fund expenditure in local NHS systems.

The National Cancer Research Institute (NCRI) recently published its findings on UK cancer research expenditure by the public and charitable sectors. This identified the small proportion (2%) of research funds allocated to prevention studies; by comparison Scotland invested 13.8% in this area. However, this is likely to be subject to considerable annual variation from project turnover and, given the scale of investment available, the necessary studies may be more appropriate to larger funders such as the Medical Research Council. NCRI also identified the relatively small spend on lung cancer (5.1%) given its high mortality rate. It will be an early objective for the Portfolio Steering Group to consider how best to address these issues.

The cancer focus group believed that Scotland could promote itself more effectively as a host for cancer trials and assigned a high priority to additional investment in trials infrastructure. The Health Department has committed £1 million annually to this, which will link with the National Cancer Research Network (NCRN) in England. NCRN aims primarily to promote recruitment of patients to phase III cancer trials. Scotland also aims to become part of the (English) network of National Translational Research Centres (NTRAC) that focus on phase I and II trials and it is hoped that a Scottish centre will be announced this year. CSO is seeking a degree of integration of these approaches, appropriate to the nature of Scottish service delivery and the distribution of its patients. These initiatives should greatly enhance the capacity for Scottish patients to become involved in trials of novel therapies and for Scotland to attract funding to host cancer trials. Five years from publication we expect that twice as many patients will be recruited annually to cancer trials.

CVD/Stroke portfolio

CSO's direct spend on CVD/stroke research projects was £1.42 million for 2002-03 (11% of CSO's total direct research spend). Of these projects, research into stroke is represented well (36.5% of total) with much of this spent on rehabilitation research. The majority of CVD projects relate to the clinical evaluation of novel markers relating to early detection, diagnosis or prognosis for CVD or prevention of CVD. CSO also supports Cochrane programmes in both stroke and Peripheral Vascular Disease, at an annual cost of £0.3 million. On top of this direct expenditure, CSO spends £5 million-£6 million annually to support the cost of CVD/stroke within local NHS systems. Research into diabetes (£150k for 2002-03) will be encompassed within this portfolio.

There are significant Scottish research strengths that should be built upon where possible. As a result, CSO has been encouraged to consider funding programme grants in both CVD and stroke that should be complementary to existing funding and might be somewhat longer in duration. Collaborative networks would be encouraged as recipients. The portfolio steering group will need to determine potential topics for such an approach and will oversee the work of a separate research group for diabetes, established following the 2002 DoH/MRC Strategy.

The aim of the portfolios is to develop a flexible and dynamic approach to support research in these priority areas.

It was felt that CSO should also explore in more detail the potential for partnerships with other organisations, particularly from the charitable sector. This theme is developed in greater detail in chapter 7.

Mental health portfolio

CSO currently supports a substantial programme of research in mental health. The range of work funded is broad, from methodological and epidemiological studies to clinical trials and systematic reviews. Annual expenditure on mental health research in 2002-03 totalled £1.73 million (c.14% of total direct research spending). Almost all of the studies in progress arose through spontaneous grant applications, but CSO instigated a core-funded programme of research at the Health Services Research Unit with a particular focus on affective disorders. Mental health research accounted for £2.8 million of the £31 million R&D Support Fund budget in 2001.

The key recommendation for the future funding of work in this area was that a 'mixed economy' of research funding was needed. As well as response mode grants, programme grants should also be available to support collaborative work on a small number of priority topics or themes. Priority topics should be broader than research questions, but more specific than clinical areas or research methods. They could either play to existing strengths, or seek to foster collaboration in areas in need of strengthening. In both cases, evidence of capacity building and collaboration between centres should be among the conditions of a programme grant. They should be chosen on the basis of relevance and feasibility as well as scientific quality.

Public health portfolio

Over 90 grants have been awarded since the beginning of 1999, representing an annual spend of some £2.87 million by the beginning of the 2002-03 financial year (22.6% of CSO's direct expenditure). Almost two-thirds of the total are for epidemiological studies. A wide range of epidemiology has been supported. Genetic epidemiology is a substantial component, as is work exploiting the potential for record linkage within Scotland, and CSO now funds two posts with the Information and Statistics Division (ISD) to provide specialist support to such studies. The intense research and policy interest in health inequalities in recent years is reflected in a number of studies of socioeconomic inequalities in health, many (though not all) involving two core funded units, the Research Unit in Health, Behaviour and Change, and the MRC Social and Public Health Sciences Unit. Much work in this area is now concerned with the way inequalities develop over the lifecourse, and CSO is funding several studies which link historic cohort data on childhood exposures with medical and mortality records. Two other important developments, which CSO is supporting with resources set aside from the Health Improvement Fund, are an extension to the Scottish Longitudinal Study linking a sample of 250,000 records across successive Censuses, and an analysis of socioeconomic and spatial variations in health using 1991 and 2001 Census data.

Other key recommendations for future funding of work in public health are for a stronger focus on intervention studies and investment in scarce skills such as statistics and health economics. CSO has already been involved in commissioning a number of studies to support policy initiatives, including evaluations of three National Health Demonstration Projects, and the evaluation of the Healthy Living Centre initiative in Scotland, but further studies of this kind are needed to redress a widely acknowledged bias in favour of descriptive and analytical studies. The Scottish public health research community is strong in social and behavioural sciences, but other disciplines, such as environmental epidemiology, require strengthening.

As well as addressing the challenge of increasing investment in intervention studies, CSO will continue to support work to improve our understanding of Scotland's health in comparison with other Western European countries, make best use of survey, Census and health service data to understand trends and patterns in Scotland's health, and address emerging public health challenges such as hospital acquired infection and antimicrobial resistance.

Research on other topics

Advances in genomic research and bioinformatics are opening possibilities to understand individuals' predisposition to disease as well as reducing the risk of adverse reaction to certain medicines. Future progress in public health will be shaped by this understanding and CSO will encourage such integrative research, reflecting its role as a funder of applied rather than basic research. There needs to be a closer relationship between the basic scientist and applied clinician researcher that should also draw upon the health data already available to NHSScotland. CSO will emphasise this theme in its public health portfolio and aim to build the necessary capacity.

CSO remains committed to supporting work that extends beyond current priorities and that helps to sustain a strong skills base across the healthcare sciences. This is developed further in the next chapter.

. . . key recommendations for future funding of work in public health are for a stronger focus on intervention studies and investment in scarce skills such as statistics and health economics.

3 Research Outside Portfolios

A large amount of CSO funding (approximately 40% in 2002-03) is allocated to areas not covered by the portfolios described in chapter 2. The research we support ranges across a very wide spectrum of topics and activities: from lung disease to antibiotic resistance, from support for the UK Cochrane Centre and Scottish-based review groups to broad programmes of Health Technology Assessment; and from dissemination of individual projects to the development of research disciplines in health economics and nursing. This diversity is a major strength of CSO, and we intend that the broad coverage will continue.

Investigator-Led/Response Mode Funding

CSO currently runs two research committees – one in Biomedical and Therapeutic Research and one in Health Services Research – which respond to proposals suggested by investigators. Approximately 180-200 outline proposals are received each year of which some 40-50 are funded. Members of the committees are also involved in assessing applications for small grants, which are designed to enable pilot or feasibility studies of ideas which may ultimately form the basis for full grant applications.

There are very strong reasons for retaining these random streams. First, many of the investigator-led proposals are born out of day-to-day practice. They are therefore likely to capture areas where there is substantial uncertainty or issues of real significance to patients, clinicians and other service providers. Secondly, this funding stream is the one which is most likely to give rise to innovative proposals. While it is important to focus effort on the major health problems, hence there are portfolios in cancer, cardio-vascular disease, mental and body health, it is also essential to allow diversity. There may be significant opportunities for health improvement outside the portfolio areas, which investigators are better placed than anyone else to identify, or an early stage. Investigators can be light on their feet, and can be quicker to spot and adapt to new key trends where an service which need a research study. Thirdly, this funding stream is important in help

Scottish researchers remain disproportionately successful in winning research monies . . .

to capitalise on early leads in Scottish biomedical and clinical research in order to reach a platform from which the research can attract major funding. It is a method of identifying and supporting innovative science that can be translated into patient benefit and it can create significant leverage to attract other research funds to Scotland. Scottish researchers remain disproportionately successful in winning research monies and it is important to sustain such success.

Clearly, some investigator-led proposals are in the portfolio areas, but many are not. In 2002-03 approximately 74% of committee expenditure (61% of total direct expenditure) was in portfolio areas.

Capacity building for topics

Core funded Units

CSO currently core funds seven research Units across Scotland, each of which has a strong topic or disciplinary focus. The total expenditure on these Units in 2002-03 was £3.2 million, which represents a quarter of CSO's direct expenditure. Four of the Units receive most of their core funding from CSO but also attract investment from the host institution and other partners, such as NES, while the remaining three are funded partly by CSO and partly by another funder. The core funding pays the salaries of staff who work on programmes of research agreed with CSO (and, as necessary, with other core funders).

Each Unit fulfils one or more strategic roles as follows: a Unit may be a centre of excellence in a field with high policy relevance; it may help to accelerate the development of research skills and expertise in a professional, disciplinary or subject area where a shortage has been identified; it may meet research needs created by policy or service developments; or it may 'plug a gap' in an area lacking a well-developed research tradition. Indeed, several Units fulfil more than one of these objectives.

All Units are expected to conduct high quality research in their respective disciplines or subjects, and to provide a source of authoritative advice on research questions related to policy and/or service development. Well-established Units are also expected to generate substantial external research income.

Although it is not possible to prescribe a 'life-cycle' that all Units will follow, core-funding will only be provided for as long as a strategic role remains, the Unit performs to a high standard, and the topic or discipline still merits core funding in the context of competing uses for CSO funds. The mechanism by which this question is decided is the regular Unit Review.

Some of the work undertaken by Units falls into the portfolio areas, while much of it could also be described as capacity building. Best estimates for 2002-03 are that some 60% of Unit funding relates to portfolio areas.

It is expected that core funding for Units will continue into the next period. However, individual Reviews will be robustly and rigorously conducted and we shall withdraw funding where the Review process recommends this.

Primary Care

Healthcare delivery continues to be strongly concentrated in the primary care sector and CSO placed much emphasis in its last Strategy on developing some commensurate research strengths. We undertook to double our investment in primary care research over a five-year period and achieved that goal after about three years. The establishment of the Scottish School of Primary Care now provides a valuable focus to research and to which longer-term commitment has been made with core support available for the life of this document.

A suite of schemes to stimulate research in primary care was launched in 1996. In 1998, funding for primary care research networks was also made available. These schemes have all now run for long enough to permit some evaluation. It is clear that they have had some success, particularly to encourage practitioners into research. However, changes to address current needs and opportunities are now timely. The networks are becoming more closely integrated with the work of the Scottish School and other schemes are being developed to support individuals – from all professional backgrounds.

The Scottish School of Primary Care has now been resourced by CSO to sustain the research activities amongst networks and is building a more integrated system, better able to support recruitment to larger projects, including clinical trials. SPPIRe (Scottish Practices and Professionals Involved in Research) will be a national network, building on regional nodes and with a multi-disciplinary membership. A database of members' interests is being developed so that support can be focused.

Nursing, Midwifery and Allied Health Professions

The Nursing Research Initiative for Scotland was established in 1994 to help to build skills amongst this large professional group. Following a second successful review it has demonstrated its ability to foster and support research from nursing as well as midwifery and some of the allied health professions. It is being actively encouraged to extend its remit in this way and is seeking a new identity that better reflects the breadth of its activities.

Choices and Challenges – the strategy for research and development in nursing and midwifery in Scotland was launched in December 2002. A comparable exercise is being conducted for the Allied Health Professions, that has yet to report. CSO is committed to working with colleagues within and beyond the Executive to achieve its aims. CSO is working with the Scottish Higher Education Funding Council in particular, as part of our statement of Strategic Alliance, to help to build greater academic strengths in these professional groups. Partnerships are also being explored with other bodies with similar objectives to broaden the range of opportunities that can be made available.

We undertook to double our investment in primary care research over a five-year period and achieved that goal after about three years.

Policy and Management

Two areas were identified as being under-resourced relative to the needs of the evolving NHS. There was felt to be insufficient research to underpin development or evaluation of policy, or organisation and management within health delivery systems. Work on the former has largely been supported by an internal evaluation unit but there is a growing sense that external, independent provision would also be valuable for both of these topics. CSO is sympathetic to this view but awaits the outcome of a separate consultation to explore wider support for these activities.

Capacity Building for Individuals

It has long been recognised within CSO that demand for individuals with the training and ability to undertake health services research far outstrips supply. Some capacity building takes place within the core funded Units. This is a particularly successful model as the Units provide a favourable environment for the fostering of research skills. Given that well established Units generate substantial amounts of external funding, the opportunity exists to employ additional junior staff, many of whom go on to pursue long-term careers in research.

However, it is recognised that capacity needs to be built at all levels – pre-doctoral, post-doctoral, and more senior positions. We recognise the concerns expressed in the Savill Report about the relative unattractiveness of clinical academic careers.

Our approach over the past several years has been to invest substantially both in PhD studentships in health services research (with approximately 15-20 students funded at any one time) and in a Research Training Fellowship scheme which has been successful in recruiting talented individuals from a diverse range of backgrounds including nurses, GPs, dentists, pharmacists and other allied health professionals as well as some from non-clinical backgrounds. (Again approximately 15 of these are active at any one time.) CSO ensures that these individuals are offered opportunities to network with each other and to learn about the process of grant application through, for example, attendance at a meeting of one of our advisory grant awarding committees.

CSO has also offered Visiting Fellowships in Public Health. Although the awards to date have been successful, demand has been limited, so we will not hypothecate funds for further fellowships as a matter of course. The office will however consider proposals on an ad hoc basis as funds allow, in areas of real skill shortage, where the appointment of a fellow might catalyse the development of a stream of work within Scotland.

In addition to its own fully-funded training, CSO has entered into partnership funding with MRC and with NES to support the training of health service researchers and clinical research fellows. We have also worked with the English Department of Health in funding a small number of Primary Care Career Scientists. Most recently, CSO has initiated a scheme designed to support primary care practitioners wishing to sustain some significant clinical activity while developing their research skills.

For the future, we intend to increase the range of awards that are offered on a partnership basis and the National Clinician Scientist Award (a scheme that will be jointly funded with both NES and the universities) has already been agreed and was announced in December 2002.

4 Research Governance

Proper governance of research is essential to ensure that the public can have confidence in, and benefit from, quality research in health and community care. A major focus of activity in CSO during the last few years has been the development of the *Research Governance Framework* published in October 2001. This document sets out the responsibilities and standards that should be applied within a formal research context. Many of the standards it sets and definitions it uses are determined by the EU Clinical Trials Directive, which must be fully implemented across the UK by May 2004 and we expect to issue a revised version of the *Framework* in 2003 that will reflect the final definitions adopted. There are implications for the system of ethical appraisal of research and for many of the local systems for managing research in organisations such as universities and the NHS. Equally, CSO itself needs to comply, with implications for its terms and conditions of grant and for the Units it supports.

Compliance with the Framework

Since publication of the document, the major focus has been on establishing the level of compliance with the Framework in research active NHS organisations and ensuring, through the production of Local Implementation Plans, that appropriate steps are being taken by organisations to achieve full compliance by May 2004. This activity will clearly continue for the immediate future. CSO acknowledges that the development of systems to meet compliance will, for some, require considerable time and effort but hope that those involved in doing so recognise the need to make decision-making processes more transparent, the allocation of responsibilities clearer and monitoring arrangements more robust.

During the consultation process, many respondents commented on the importance of research governance but also reflected concerns about how best to resource it. CSO views compliance as an essential mechanism to support patient safety and has therefore explicitly built this element into the future funding formula for NHS bodies under Research Governance and Management.

In autumn 2002, two teaching Trusts put themselves forward for voluntary inspection of their clinical trials arrangements by the then Medicines Control Agency (now Medicines and Healthcare Products Regulatory Agency). Although much was of high quality, areas for improvement were identified. Since such inspections cease to be voluntary when the EU Clinical Trials Directive is fully in force, CSO wishes to draw general lessons from the feedback and take such steps as may be necessary nationally to support robust trials management for NHSScotland patients. One obvious aspect is to encourage more NHS staff to train to Good Clinical Practice standards.

Management Issues

The increasing importance attached to governance has implications for the scale of research that an organisation undertakes before the investment in the necessary infrastructure can be justified. This may appear to conflict with CSO's previous policy of seeking to encourage research activity in local NHS systems without this tradition. There is clear evidence that overall patient care is improved in research active environments and, as a result, CSO continues to support its previous policy. However, to comply with research governance, NHS Boards will either need to dedicate disproportionate resource to meet governance requirements or to develop partnerships with other local NHS bodies so that the costs of the governance infrastructure can be afforded between them. The latter is clearly to be preferred and offers wider opportunities for collaboration and cost sharing. CSO will continue to work with NHS bodies to build research partnerships.

Ethics under Governance

Governance arrangements for NHS research ethics committees (RECs) in Scotland were also published in October 2001. This is a subset of the Research Governance Framework and is a distillation of current good practice and the conditions which NHS RECs need to fulfil to comply with the EU Clinical Trials Directive. Because, within the European Union, the UK is the Member State, the Directive has to be implemented by the Westminster Parliament for the whole of the UK. Scotland, England, Wales and Northern Ireland will have to have systems that are compatible because, after May 2004, any REC recognised to ethically review clinical trials will effectively have UK-wide jurisdiction. CSO is working closely with the Central Office for Research Ethics Committees (COREC) to ensure this is the case. While there might be some variations in internal process in individual countries, basic principles and major operational issues need to be identical.

Consumer Involvement

The *Research Governance Framework* encourages public participation at various stages of the development and execution of research projects, where appropriate. CSO has had some lay representation on the Chief Scientist Committee for several years, thus ensuring public input to development of CSO's strategic direction. Working through the Association of Local Health Councils it has also trialed using lay reviewers for health services research committee applications. A list of volunteer reviewers was developed with the Association. They were invited to review items on the agenda over a period of some two years. In practice, reviewers found

CSO has more than a dozen individuals, from diverse backgrounds, interested in being involved with its work.

this difficult to do effectively and if direct input on individual proposals is to be pursued, some well-tailored training will be needed. The Association had not felt able to contribute similarly to the work of the Biomedical and Therapeutic Research Committee.

More recently, the Chief Scientist created a sub committee of the Chief Scientist Committee to advise him on the role that the public, as consumers, might play in the work of CSO. Good progress is being made. Following advertisements in the press, CSO has more than a dozen individuals, from diverse backgrounds, interested in being involved with its work. During the early part of 2003 three training days were held. These gave the volunteers information about the detail and scope of CSO responsibilities and also equipped them with skills to enable them to make a meaningful contribution to CSO committees and to offer a view on other aspects of the work of the office. Much will be learned by experiment and experience about the best way for members to participate. It will be important to ensure that members of this group continue to receive on-the-job training and support as necessary.

5 Support for Local NHS Systems

Supporting research in the NHS is a key activity for CSO. Not only are almost 75% of CSO funds deployed in this sector, but the active engagement of NHS clinicians is essential if we are to deliver practical solutions on matters of relevance to the people of Scotland. In particular, Health Services research must be founded in, and reflect the priorities and needs of, those operating in that critical interface with the public.

R&D Support Fund

The bulk of CSO research funding in the Health Service is awarded through the R&D Support Fund. The introduction of this funding stream in 1998 followed a major exercise to capture information about the uses to which the Additional Cost of Teaching (Research) budget was put. The largest cost identified was staff time, but significant direct clinical costs of supporting research activity were also identified. The fund's introduction gave Trusts a new insight into their research activities and allowed them to be managed for the first time. Until then research had been largely a subliminal activity, subject to little, if any, scrutiny or management. Local NHS management now has greater insight into the full range of activities for which they are responsible. These responsibilities were further clarified by the *Research Governance Framework*.

Quantifying these costs, however, was not always matched by an ability to deploy them where they can have greatest impact. Few in the NHS are full-time research workers and the great majority are able only to give a small fraction of their time to research. This factor alone has made financial management difficult in some Trusts, since, in practice, it has proved difficult fully to disaggregate research costs from those of general care. The resultant difficulties in research management, particularly in larger Trusts, are obvious. At both a local and national level, this has frustrated the ability to manage research resources and activity effectively and threatens to undermine the Concordat that the NHS has with the Health Departments and the Medical Research Council.

NHS Support for Science

For the above reason, CSO reviewed the operation of the NHS R&D Support Fund in 2000. It concluded that in future there should be two main drivers for research funding in the NHS – quality and focus – and that the Support Fund should be replaced by a new Support for Science budget. The Review concluded that quality should be taken as a prerequisite in attracting externally funded non-commercial research, and that a larger proportion of NHS research funding should be used to support NHS priorities. Within these parameters, it recommended that allocations should be formula-driven and linked to the externally funded research activity of Trusts, with funding directly linked to high quality research outputs.

Funding formula

An underpinning principle to deliver these aims is that research funding must be seen, managed and accounted for as a distinct stream of funding. While recognising the aforementioned difficulties in dis-aggregating research costs from those of general care where staffing issues arise, there are other elements of research funding where costs can, and should, be accounted for more directly. One such area is the direct cost of supporting additional clinical activities that arise purely as a consequence of research. Such costs are peculiar to individual research projects and as such are irregular. Nonetheless, Trusts have, in the past, accounted for a substantial proportion of their R&D Support Fund in this area by calculating such costs as a proportion of indirect or total research costs. CSO therefore intends introducing new arrangements to ensure that such costs are separately accounted for and more accurately quantified.

We are indebted to many for their contributions to developing the funding formula being used for the first time from April 2003. The development of these proposals was undertaken with the active participation and support of the NHS and led to the conclusion that activity should be measured in two ways: staff involvement in leading or collaborating in research (as a measure of the direct and indirect cost of supporting research) and the number of participants recruited to trials (as a measure of additional direct clinical costs to the NHS of supporting research). The latter has proved difficult to do in practice but it remains our view that some measure of work 'volume' is a necessary element of the formula. We shall continue to work with the NHS to develop this aspect.

NHS Priorities and Needs

A feature of NHS research, however, is the significant amount of work, instigated and undertaken by clinicians, without an external funder or peer review. Such research accounts for approximately 20% of the Support Fund. This research therefore does not meet the Support for Science standards of quality assurance and lacks any mechanism to focus its activity. This raises potential conflicts with CSO's stated aim of increasing its focus on research into areas of clinical relevance, both to test out issues of possible future relevance and to develop the evidence base on the value or effectiveness of clinical procedures. That is not to say that much of this work is not in areas of relevance or of acceptable quality; there are, however, no mechanisms in place to ensure that this is the case; such mechanisms will be necessary to comply with research governance.

For this reason, the second new CSO funding stream, *NHS Priorities and Needs*, makes provision for NHS Boards to group their research not meeting the Support for Science criteria into NHS Programmes. Such Programmes, focused on NHS priorities or NHS needs, will each have an NHS Programmes leader who, over time, will agree the strategic direction of the work

Health Services research must be founded in, and reflect the priorities and needs of, those operating in that critical interface with the public.

with CSO and approve the research activity coming within them. Such activity will encompass both 'own account' work and externally-funded research by organisations which do not meet the Support for Science eligibility criteria, e.g. local endowment funds, overseas charities. In doing so, Programmes will meet the dual criteria of quality and focus and will make an important contribution to the work of the portfolios outlined in chapter 2. It is recognised that there is a very wide range of research led by researchers in the NHS that is intended to respond to NHS needs, but it is not organised around coherent themes. Over the next five years, CSO will work with local NHS systems to structure this activity into agreed research themes.

Programmes of Research in local NHS systems

A start was made in this area in 2002, with Trusts structuring their research activity into broad groupings of research activity. In total, CSO has approved 65 such groupings across Scotland as Programmes. It is already clear that there is scope for some rationalisation in terms of both function and scale. CSO will work with local NHS systems to deliver these objectives. As part of that process, CSO will also wish to satisfy itself that effective arrangements are in place to manage both the research and financial consequences of these Programmes. The aim is to have in place, by 2006, a network of NHS Programmes across Scotland which exercise full financial and managerial control of the research they contain, and which are subject to transparent and robust assessment procedures.

A prerequisite for Programmes will be evidence that the NHS Board (or group of local NHS bodies) is capable of managing the work to a high standard and delivering outputs within a framework of research governance and performance management. Local NHS systems with small numbers of research active clinicians have been encouraged to build research partnerships with others so that meaningful programmes can be created with sufficient critical mass. Such alliances are also being encouraged to meet the requirements of the *Research Governance Framework*. In recognition of the important contribution made by smaller organisations, it remains a CSO objective to help to support and stimulate research activity in all local NHS systems. Not only does this help to improve patient care but it also helps to motivate, retain and recruit able staff outside the traditional teaching hospitals.

Financial Implications

These two new funding streams, *Support for Science and NHS Priorities and Needs*, will ensure that the NHS research effort is appropriately focused and – equally importantly – equitably funded. The latter will inevitably mean that funds will move from one NHS Board to another in line with their research activity. CSO is alert to the difficulties local NHS systems might face if the movement of funds is significant or sudden and, as a consequence recognises that any shifts in resourcing need to be progressive. For that reason, the financial consequences, of these new arrangements will be phased in over a three-year period until March 2006. CSO believes that this measure should provide individual NHS Boards with a sufficient degree of funding stability, while at the same time allowing funds not currently focused on supporting externally funded non-commercial research to be re-allocated and targeted on NHS Programmes. The consequence of this incremental shift of funding is that the direct funding of NHS Programmes will similarly need to be phased in up to 2006.

6 Shaping Change

Research is at the heart of the modern NHS, shaping and informing change. Although it is not the direct function of a research funder to implement the findings of research or to disseminate best practice, it does have a legitimate and important role in ensuring that NHSScotland has the necessary evidence to support decision makers and to inform policy and practice.

SIGN is one of several Scottish bodies that synthesise primary research; others include the Health Technology Board and the Clinical Standards Board for Scotland, now combined within NHS Quality Improvement Scotland. In the past, CSO has funded little secondary research outside its research units and its significant support for the Cochrane Collaboration. The latter remains a considerable commitment for CSO. Scottish-based groups have been encouraged to consider how best to demonstrate value for money given the long-term nature of their funding and the eventual expectation of patient and healthcare benefits. It will become increasingly hard to justify continued support if such benefits are not visible in the life of this document.

Equally, CSO needs to work closely with bodies such as SIGN and NHS QIS to understand their research needs and to work with other funders and the research community to help to address them. CSO, as part of the steering group of the UK Cochrane Centre and the comparable body for QIS will be able to promote such two-way information flows. It will be important to help to ensure that the work of QIS is informed by the most up-to-date knowledge. However, we recognise that this has the potential to create a sizeable agenda that will need to be managed by the Portfolio steering groups, in particular, to determine how resources should best be used.

In the past, CSO has focused the great majority of its grants on primary research studies. As one of the three largest Scottish Executive funders of the science base we would wish to sustain this emphasis to our grant giving. However, this approach inevitably makes the task of demonstrating the benefits of investment more subject to delay and inaccuracy. CSO spends 0.67% of the total cost of the NHS and the choices explored in this Strategy aim to ensure that we achieve the greatest benefits from it. However, the current policy of focusing research expenditure on primary research may need to be reviewed in the life of this strategy.

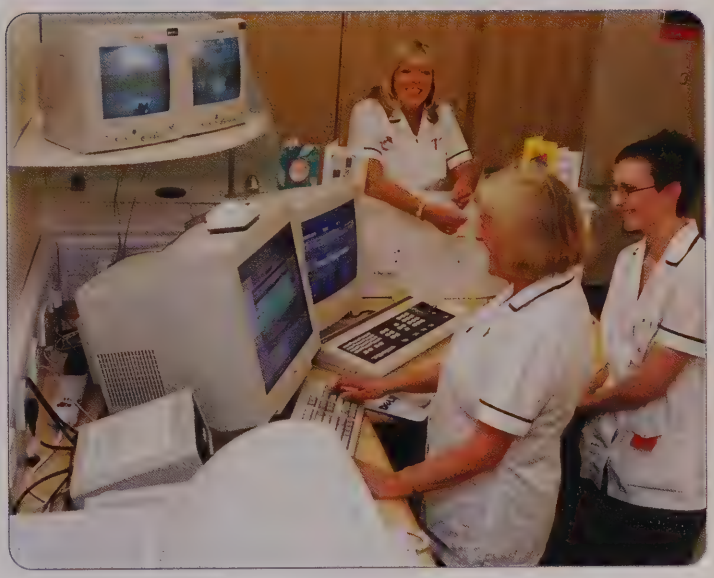
There is also concern for research that is able to bridge basic science and applied clinical studies – translational research. CSO will play its part and work with others to achieve a more seamless delivery from the laboratory to the patient. A model is already available for cancer and translational studies will be part of the programmes of work conducted by the new Scottish Cancer Trials Research Network.

Translating Research into Practice

The *Research Governance Framework* emphasised the importance that a public sector research funder, such as CSO, attaches to ensuring that research findings are subjected to peer review scrutiny (e.g. as part of producing refereed publications) and put in the public domain. However, refereed publications are not the only worthwhile output and, on occasion, should be actively deferred. CSO has responsibility for developing policy on intellectual property (IP) for NHSScotland and helping to foster a climate that recognises the potential that ideas or 'IP' may have.

Results into Evidence

Much of the work funded by CSO contributes to the general pool of knowledge through refereed publications. It is generally acknowledged that there can be intervals of many years between publication and adoption of findings. This is partly explained by the need for the results from individual publications to be corroborated and a body of evidence to accumulate.



CSO recently supported a study to evaluate the extent to which guidance produced by the National Institute for Clinical Excellence (NICE) and SIGN drew upon our research and their rapidity of uptake. This demonstrated that the median time between publication and citation by SIGN was just over five years (which is similar to citation by a UK biomedical paper in the Science Citation Index). By comparison, NICE reports were based on work that had, on average been published 3.3 years earlier; clearly this reflects their rather different purposes. Of the UK papers cited in SIGN guidelines, about a third had been funded from a UK Government source: SEHD – 6%; DoH – 13%; MRC – 14%. SEHD funded work was disproportionately cited in SIGN reports (six fold) and by NICE (two fold). This emphasises the relative importance of local research funding and its ability to be relevant.

One of the Cochrane review groups supported by CSO until its recent move to Canada was that for Effective Practice and Organisation of Care (EPOC). While its work continues, many questions about effective implementation remain and CSO needs to consider, with other funders, how best to address the current lack of understanding in this area. Delays to implementation are not unique to healthcare but may

CSO will play its part and work with others to achieve a more seamless delivery from the laboratory to the patient.

perhaps be exacerbated by delivery being chiefly through a single large organisation. The EPOC group will continue to explore good practice in the field of healthcare. However, other fields might provide insights into better methods to facilitate implementation of research and other professions (such as marketing or psychology) might provide new models that help to promote change. CSO will be exploring with other funders and the research community how best to tackle this issue.

As outlined above, CSO regards it as a principle of research governance that findings supported by the public purse should be readily accessible in the public domain. Our terms and conditions of grant emphasise the importance attached to proper publication in refereed journals. In support of this general policy and in order to increase awareness of research findings, CSO now posts executive summaries of recently completed projects it has funded on its website. The aims of these summaries are:

- to disseminate research findings and implications to policy makers and health service managers in a form which is more user-friendly;
- to encourage researchers to consider how their findings may contribute to the development of health service policy and practice.

CSO shall also encourage the Portfolio Steering Groups to consider dissemination as they will be well placed to identify key results relevant to healthcare delivery and target suitable audiences.

Technology transfer

Technology transfer is the process of encouraging the utilisation of technology, expertise, know-how or facilities. Technology transfer can result in product/process improvement or commercialisation, in either the intended or different areas of application. NHSScotland has a vast and valuable range of expertise with a corresponding potential for technology transfer which is largely unrealised. In acknowledgment of this, Ministers announced in *Our National Health: A Plan for Action, A Plan for Change* their intention to establish a technology transfer office for NHSScotland. During the last two years we have worked in close partnership with the two Scottish Enterprise Agencies and NHS Bodies to bring the technology transfer office into being as a commercial entity. This was launched as *Scottish Health Innovations Ltd (SHIL)* in October 2002.

SHIL has also benefited from a consortium of Scottish NHS Trusts applying successfully for Public Sector Research Exploitation funds from the Department of Trade and Industry. This, combined with funding from CSO and the two Enterprise Agencies, will help to support and inform the commercial potential of NHS innovations. This support is available to any subscribing NHS body.

SHIL will also encourage 'knowledge management' by raising the awareness of useful ideas that, while unlikely to generate a financial reward, will nevertheless have potential to improve care by improving efficiency, effectiveness or saving costs. Through its support to NHSScotland for the wider dissemination and commercialisation process, *SHIL* will be able to provide wide ranging support services.

In the slightly longer term, it is anticipated that the increasing experience and expertise in NHS Boards will allow SHIL to focus its activities on providing a single point of entry and negotiation for NHS-related IP in the more specialised services of marketing and commercial negotiation.

In addition CSO has committed up to £1 million towards co-funding any Scottish projects that are funded through the new Health Technology Devices (HTD) programme. The Department of Health has promised up to £12 million for this six-year programme and public sector funding will be matched by industrial partners. This follows on from the MedLINK programme and the overall objective is to develop new medical devices and healthcare technologies that are capable of exploitation by the healthcare industries to yield improved benefit to patients and a more robust UK medical devices sector.

Intellectual Property Rights

It is only in the last four years that the NHS has had a policy of aiming to identify, protect and exploit its intellectual assets. In that time, a significant cultural change has been instigated. Research-based innovations are key assets of the NHS. CSO policy on intellectual property, which is set out in its IP Policy Framework document, recognises that the NHS has a responsibility to help ensure that its Intellectual Property (IP) can be appropriately exploited either within the NHS or by others. This means that NHS Boards must have arrangements in place to identify, exploit and protect the Intellectual Property Rights (IPR) that they generate.

CSO will support the exploitation of IP by issuing guidance to NHSScotland on policy, employment and financial aspects of IP management. In particular, the guidance will recommend the development of sharing the financial benefits of exploitation with those responsible for its development.

Innovations often need further research, development or investment to demonstrate that they are suitable for use in practice. The Proof of Concept Fund, from Scottish Enterprise, aims specifically to address this potential gap and those in the NHS are eligible to apply. Naturally, if the concept is proven sound and is commercially viable the expectation is that public sector support withdraws and commercial investment is sought.

The ability for NHS bodies to select the most appropriate exploitation route is currently hindered by statute which does not allow them to form or participate in the formation of companies set up to exploit their innovations. Ministers have considered this limitation and decided that it is an unnecessary barrier to effective management and exploitation of IP. At the earliest opportunity, Ministers will seek to amend statute to allow NHS bodies the necessary freedom for the effective exploitation of IP.

CSO-Funded Research

Although CSO currently retains the IP for the research projects it funds, it has been considering whether this policy should be amended better to exploit IP generated by the research it funds directly. The Baker Report and the Government's response to that document both suggest that intellectual property generated through any research contract should belong to the body best able to exploit it, which is typically felt to be the research provider. There are clearly exceptions to this general rule and, indeed, this is recognised in the Government's response. It is also important to ensure that the research providers have the necessary expertise to manage this IP – until last year this has been the exception rather than the rule in the NHS. Nonetheless, the general policy is worthy of support.

CSO has been considering how best to amend its funding criteria and awards to ensure best use of the results of CSO-funded work. The majority of Principal Investigators are based in universities and many of these institutions now have well resourced Research Offices. Similarly, now that NHS Boards are able to draw upon the expertise of *SHIL* they too have an appropriate source of advice. Thus, although details vary, most if not all researchers funded by CSO would have access to some expertise to support protection, management and exploitation of IP arising from research. As a consequence, it now seems timely to alter our former arrangements. IP arising from CSO-funded research will therefore be assigned to the host institution on the condition that it seeks to protect and appropriately exploit it. However, CSO will retain the right for a period of two years following the completion of the award to reclaim the IP if it is of the belief that the IP has not been adequately exploited.

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[1] Creating Knowledge & Creating Wealth: Realising the economic potential of public sector research establishments – John Baker, August 1999.

7 Partnerships

Within the Executive and its Agencies

CSO is one of three science budgets within the Executive. The largest is that from the Enterprise and Lifelong Learning Department (SEELLD) to the Scottish Higher Education Funding Council (SHEFC) that makes multi-disciplinary provision, while CSO and its equivalent division in the Environment and Rural Affairs Department (SEERAD) have more specific objectives. The *Science Strategy for Scotland* emphasised the important role that they foresaw for science in developing the Scottish economy and identified a number of obstacles to be overcome and issues to be addressed. It also heralded the Scottish Science Advisory Committee that *inter alia* looks for complementarity across the range of scientific support from the Scottish Executive. CSO is working with the Committee as it develops its understanding of the interactions amongst different parts of the Executive.

CSO already has both formal and informal liaison with both other science funders in the Executive. There are occasional strategic meetings with SEERAD as well as many more detailed discussions about individual research proposals. These should continue. Over the last few years some of the Agricultural and Biological Research Institutes that SEERAD support have refocused their work towards areas of greater relevance to human health. For example, the Rowett Research Institute is now working with clinical collaborators to investigate the basic biological mechanisms underpinning nutrient metabolism in animals and humans. Other SEERAD sponsored organisations are keen to establish research links with the healthcare research community. CSO is working with SEERAD and its Institutes to facilitate these developments and strengthen the synergy between the work each Department supports.

There are several formal interactions with SEELLD that include research but also extend to education and professional training. Common concerns about the need to revise the format of the Research Assessment Exercise RAE will be an important aspect of joint working in the immediate future. CSO is already working with colleagues in the English Department of Health to ensure that the forthcoming review of RAE is fully informed of the issues relevant to the healthcare Units of Assessment.

CSO has developed an increasingly fruitful dialogue with the Scottish Higher Education Funding Council that led to a *Strategic Alliance for Health and Community Care* being signed and taking effect from January 2002. This sets out the common interests in relation to research and the skills base in disciplines relevant to health and healthcare. The Scottish School of Primary Care was an early product of our joint working, with each partner investing £600k over three years to develop sustainable research strengths in primary care. It is still too early formally to evaluate the success of these investments. Although early developments are encouraging, some longer-term commitment from the university sector will be essential for benefits to be sustained.

A wider partnership has been established to take forward some of the recommendations of the recently published *Choices and challenges – The strategy for research and development in nursing and midwifery in Scotland*. This report recognised that there would be little benefit in the medium to long term from research training if developed in isolation. It recommended that attention be given to securing career pathways that blended clinical and research responsibilities. A partnership involving CSO, Nursing Directorate, SHEFC and NES is considering how best to implement these recommendations. Each organisation will be finding new investment to make in this area in the next few years, recognising that additional supervisory skills will be an essential first step on which to build. A research strategy for allied health professionals will aim to build upon and extend this work.

Partnership with the Scottish Council for Postgraduate Medical and Dental Education (now NES) has promoted fellowships and lately, with University support, the Clinician Scientist Scheme in Scotland. This builds on shared concerns about the need to attract able young clinicians to develop and sustain their research activity.

Universities and the NHS

Partnership with academic and healthcare organisations are the bedrock of CSO's activity. They remain crucial partners to the delivery of this strategy, providing the infrastructure, trained personnel and multi- disciplinary skills that will be needed if its objectives are to be achieved. The development of the Clinician Scientist Scheme embodies this partnership and should help to strengthen the Scottish science base.

In the same way that university-led research funded by CSO will, as a matter of course, be expected to have NHS collaborators in all projects of relevance to the NHS, it is important for local NHS systems to develop NHS/academic collaborative groupings to broaden their experience and be in a position to best address research topics. For that reason, there is an expectation that all NHS Programmes will have an academic link, collaborating and contributing to the general direction of the research activity as well as specific projects within those Programmes.

It will become increasingly important to look for common interests with others and be more entrepreneurial in exploring alternative funding models if we are to sustain the current breadth and depth of activity.

Other Research Funders

The four UK Health Departments continue to have much in common and research issues are often best addressed through jointly developed or similar policies. There is extensive dialogue, both formal and informal, seeking to ensure complementary activities and to avoid unintended duplication of effort. Since some aspects remain reserved to Westminster, such dialogue also ensures better understanding and an opportunity to develop a shared approach.

There are long established Concordats with most of the Research Councils that are reviewed annually and substantially revised every five years. These ensure mutual awareness and encourage joint working on topics of common interest. Most importantly, they help to secure a spectrum of funding from basic studies (supported by the Research Councils) through to applied research (typically supported by Government Departments such as CSO).

CSO is a member of the Funders Fora for cancer, coronary heart disease and ageing and older people. These bring together the research directorates of all four UK Health Departments, the MRC, other research Councils (Forum for ageing and older people), the Wellcome Trust, industry and other sizeable research funders from the charitable sector. The Fora increasingly allow better strategic planning and enable joint working amongst two or more members. CSO intends to develop these relationships more explicitly in the life of this strategy and look for opportunities to address Scottish problems and needs with other interested parties.

The UK-wide collaborations entailed in NCRI membership were described in chapter 2. Scotland is already a member of NCRN and is selecting by competitive tender those to participate in NTRAC. The two networks will have common oversight in Scotland and will be embedded in the regional structures established to deliver clinical care in cancer.

Beyond the funders fora described above, CSO does not have similar liaison arrangements with the larger healthcare research charities. However, some dialogue has been established with many members of the Association of Medical Research Charities (AMRC) as a result of working through the implications of the *Research Governance Framework* with them. CSO believes it would now be timely to consider creating a more regular forum for debate with AMRC and its members.

There is a long-established dialogue with the Scottish Hospitals Endowment Research Trust (SHERT) for whom we act as sponsor department while they attract Non-departmental Public Body status. This interaction explores common areas of interest and fosters complementary funding where appropriate. For example, both bodies have long-standing interests in capacity building but have focused on different sectors. CSO also provides advice to SHERT on grant applications through its Biomedical and Therapeutic Research Committee.

The Public, Patients and Consumers

The need for closer partnership with patients and consumers was encouraged in the *Research Governance Framework*. A start has been made (see chapter 4) and progress will be sustained in the life of this strategy. The immediate agenda will need to focus on achieving greater clarity about the most appropriate ways in which patients and consumers can contribute to the work of CSO. This may prove to be better at the strategic and general level than that of individual projects. The scientific community may also require some re-assurance to accept their critique of a proposal.

Industry

The pharmaceutical industry invests significantly in research but few of the large companies are strongly represented in Scotland. Recognising that devolution might result in this important industry becoming less well informed about research opportunities in Scotland CSO established a Pharmaceutical Liaison Group in 2000. Membership of this group is offered to representatives from all large pharma companies and the Association of the British Pharmaceutical Industry. It meets approximately twice annually to explore matters of joint interest or concern and a number of possible collaborations are under discussion.

It will become increasingly important to look for common interests with others and be more entrepreneurial in exploring alternative funding models if we are to sustain the current breadth and depth of activity. Although all current partnerships are with other UK organisations, international collaboration and co-operation is under discussion. Countries such as Canada and Finland have common concerns and opportunities to work together with some of their research funders should be instigated. This might not only allow larger studies to be funded but also support natural experiments that exploit inherent differences in healthcare systems or policy environments.

Annex 1 Achievements against past Objectives

Work with others to identify topics which are important to the NHS and health improvement, and amenable to research and Seek to improve research links between the Universities and the NHS in Scotland

SSPC founded in 2000 with significant investment by bodies including SCPGMDE (now NES), the Executive and SHEFC.

Commission studies in areas of particular importance

A sum of £1.2 million (provided jointly by CSO and SHEFC) has supported a range of topics commissioned in support of primary care and managed through the School. These were selected on the basis of scientificquality, sustainability and capacity to increase the skills base in the topic.

Promote a multidisciplinary approach to health services research

This is a strategic objective for use of the Support Fund and is actively encouraged. In the most recent data collection exercise from recipients of Support for Science funding an increasing breadth of health service professionals are now engaging with research, typically in multi-professional teams.

Some professions are still relatively under-represented (e.g. Nursing and Allied Health professions) and CShas also worked closely with colleagues in the Scottish Executive, particularly in the Health Department in support of common interests. Most recently, with the Nursing Directorate to help to develop and implement their Strategy.

Help implement relevant research findings

Dissemination is actively encouraged as a condition of any CSO award and the published output from CSO research grants is good.

The Technology Transfer Office has been established as Scottish Health Innovations Ltd.

Strengthen the system of Research Ethics Committees appraisal

Significant progress has been made. Scotland established a second multi-centre REC in May 2002 to act as The Ethics Committee under the Adults with Incapacity Act whilst also sharing the work of the original MREC. A UK-wide exercise to co-ordinate compliance with the EU Clinical Trials Directive is progressing to schedule.

Ethics are a key component of research governance and *A Research Governance Framework for Health and Community care* was published in November 2001. All NHS Trusts in Scotland in receipt of significant Support for Science funding are now meeting its conditions.

Encourage co-operation between research consortia; primary care and hospitals, using the Support Fund and other resources

SSPC won c.£700k investment over three years from a consortium of Scottish PCTs and facilitates the research evaluation of NHS 24.

Support Funding to Greater Glasgow Primary Care Trust to help develop a mental health research network amongst Trusts in the western region.

Restructure the research grants advisory committees
The research grants advisory committees were restructured in 1998 and the structure continues to serve well. CSO remains committed to the principle of robust peer review for all of its funding.

Maintain support for high quality projects proposed by individual researchers and groups
This has been achieved, with the proportion of expenditure committed to grant awards remaining relatively stable over the period. Final reports received in the last five years have continued to be of a generally high standard with 63% being rated as excellent or good/very good. CSO encourages publication in quality peer review journals and the mean output from a CSO grant is 2.6 refereed publications. Thus the typical cost to CSO for each such publication is <£16k; a very impressive statistic.

Annex 2 Consultation Process

The last Strategy was published in 1998, with an anticipated five-year currency. The revision was therefore started in the summer of 2002, to allow for much informal group consultation and two formal general consultation periods. The first, concluding in October 2002, invited views about how the strategy should change, how its priorities should be modified and, particularly, how CSO should get best value from the funding available. This process had been informed following discussion at the Biomedical and Therapeutic Research Committee (one of our two grant advisory committees).

The 2000 Review had proposed Portfolio management of several key priorities and it seemed important to help inform their development as part of the process of revision. Four portfolios had been proposed in: Cancer; CVD/Stroke; Mental Health; and Public Health. More detailed views were sought from the research community about where progress might most rapidly be made and how CSO could best contribute. Responses about Public Health were sought during meetings with opinion leaders in the research community held during October 2002 by Professor Last acting on CSO's behalf. A group of researchers reflecting the discipline spread of the topic were invited to two meetings with CSO to address the same issues. The first meeting was held before the consultation deadline and the second shortly after, when some feedback from respondents helped to inform discussion.

A total of 58 responses were received in the first formal consultation from a wide range of individuals and organisations in academia, the NHS, patient/consumer groups, Royal Colleges and from policy colleagues. A summary of responses was similarly discussed at the October meeting of the Health Services Research Committee. All forms of feedback helped to inform a draft that was discussed at the November 2002 meeting of the Chief Scientist Committee.

Consultation on the revised document closed in April 2003 (Annex 3 lists recipients). A total of 48 responses were received, the majority of which were supportive of the proposals, in whole or in part. We are grateful to all those who took the time to respond; details can be found on our website – http://www.show.scot.nhs.uk/cso/index.htm

Annex 3 List of consultees

NHS Scotland
Health Board Chief Executives
Trust Chief Executives
Trust & Board R&D Lead Officers
Directors of Public Health
Special Health Boards
Public Health Institute for Scotland
Local Health Councils
Scottish Needs Assessment Programme
Scottish Intercollegiate Guidelines Network
Scottish Centre of Infection and Environmental Health
Multi-centre Research Ethics Committee administrators
Local Research Ethics Committee administrators

Other Public Sector/Healthcare
Healthcare Trades Unions
CoSLA and Local Authorities
Royal Colleges
Hospices
Copyright libraries

Academia
University Principals
Postgraduate Deans of Medicine
Deans of Medical Schools
Deans of Dentistry
Heads of Academic Nursing and related Departments
Pharmacy Departments
Centre for Research into Socially Inclusive Services
Research Units
Scottish School of Primary Care

Other Research Funders
Research Councils
Association of Medical Research Charities
Wellcome Trust
R&D Di

Parliamentary
Scottish MEPs
Clerk of Health and Community Care Committee
SPICe Library

Chief Scientist Office Committees
Chief Scientist Committee
BTRC members
HSRC members
Pharmaceutical Liaison Group
Training Award Committee members
Public Participation Group

Voluntary Sector
The Action Group
Age Concern Scotland
Alzheimer Scotland - Action on Dementia
Breast Cancer Care
Breast Cancer Research
Advice Service Capability Scotland
Chest, Heart & Stroke Scotland
Cornerstone Community Care
Counselling & Physiotherapy in Scotland
Deaf Connections
The Edinburgh & East of Scotland Deaf Society
Equal Opportunity Organisations
The Foundation for People with Learning Disabilities
Manic Depression Fellowship Scotland
Psoriatic Arthropathy Alliance
Stirling & District Association for Mental Health

Annex 4 Glossary

allied health professions – those professions outwith doctors and nurses who work with patients in the healthcare team (Arts therapist, Dietitian, Occupational therapist, Orthoptist, Physiotherapist, Podiatrist, Prosthetist/ Orthotist, Radiographer, Speech and Language therapist).

bioinformatics – any use of computers to handle biological information. Synonymous with "computational molecular biology" – the use of computers to characterise the molecular components of living things.

capacity building – increasing the number of researchers, and their skills, in a particular field.

CHD – coronary heart disease.

Cochrane programmes – the Cochrane collaboration is an international organisation named after Archie Cochrane who fostered preparing, maintaining and ensuring the accessibility of systematic reviews of the effects of health care interventions. Completed reviews are collated in the Cochrane Library.

COREC – Central Office for Research Ethics Committees.

direct support costs – additional clinical costs incurred by an NHS organisation solely due to participation in a research project, eg an extra blood test or X-ray taken purely for the purposes of the research and not part of the normal process of care.

DoH – Department of Health in England.

epidemiology – the study of the distribution and determinants of health-related states and events in populations and the control of health problems.

EPOC – Effective Practice and Organisation of Care, part of the Cochrane collaboration.

EU Directive – Directive 2001/20/EC of the European Parliament relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

HTD – Health Technology Devices programme.

IP intellectual property/IPR intellectual property rights – novel or previously undescribed tangible output of any intellectual activity. It has an owner and can be bought, sold or licensed and must be adequately protected. It can include inventions, industrial processes, software, data, written work, designs and images.

MRC – Medical Research Council.

National Institute for Clinical Excellence – a Special Health Authority (England and Wales), its role is to provide patients, health professionals and the public with authoritative, robust and reliable guidance on current 'best practice'.

NCRI – National Cancer Research Institute; the funders forum for cancer.

NCRN – National Cancer Research Network, part of NCRI.

NES – NHS Education for Scotland.

NHS QIS – NHS Quality Improvement Scotland.

NTRAC – National Translational Research Centres, part of NCRI.

own account research – research initiated and undertaken by clinicians without any external funding source.

Phase I trial – tests a substance in a limited number of healthy people to learn whether it is safe to take and what happens when it enters the body.

Phase II trial – tests a substance in a limited number of patients to see if it is effective in a particular condition in the short term.

Phase III trial – tests a substance in a large number of patients, often in many hospitals. These trials compare the substance with a treatment already in use, or if there is no treatment currently available, with a placebo.

programme grants – are longer-term grants to support research aiming to answer an interrelated set of questions.

R&D – Research and Development.

REC – Research Ethics Committee.

record linkage – computerised links of healthcare planning data items relating to the same person, household or business unit. This report discusses the use of record linkage for statistical purposes only, to produce summaries and population/community statistics.

RAE, research assessment exercise – an assessment of the quality of research conducted within Higher Education Institutes and conducted every four-five years. Future funding levels are based upon its results.

research governance – application of general governance principles to research. Includes: enhancing ethical and scientific quality, promoting good practice, reducing adverse incidents, ensuring lessons are learned, preventing poor performance and misconduct.

response mode grant – a grant allocated on the recommendation of one of the Research Advisory committees to fund a project proposed by a researcher.

R&D Support Fund – meets the infrastructure costs to the NHS of being research active, in particular hosting externally-funded, non-commercial research.

SEELLD – Scottish Executive Enterprise and Life Long Learning Department.

SEERAD – Scottish Executive Environment and Rural Affairs Department.

SEHD – Scottish Executive Health Department.

SHEFC – Scottish Higher Education Funding Council.

SHERT – Scottish Hospitals Endowment Research Trust.

SHIL – Scottish Health Innovations Limited, the technology transfer office for NHSScotland.

SIGN, Scottish Intercollegiate Guidelines Network – consortium of royal colleges that develops and disseminates national clinical guidelines containing recommendations for effective practice based on current evidence.

technology transfer – the process of encouraging the dissemination and use of technology, know-how, expertise or facilities.

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